IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

APOTEX, INC., Plaintiff, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-2768
GIANT EAGLE, INC., Plaintiff, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:10-cv-5164
WALGREEN CO., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:09-cv-3956
RITE AID CORPORATION, et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:09-cv-3820

Goldberg, J. **June 8, 2017**

MEMORANDUM OPINION

In Federal Trade Commission v. Actavis, 133 S. Ct 2223 (2013), the Supreme Court wrestled with the complexities of how a reverse-payment patent litigation settlement fits within an antitrust context. Ultimately concluding that a rule of reason analysis applies, the Court stressed that the "structuring of the present rule-of-reason antitrust litigation" must be left to the trial court. This Opinion sets forth such a structure where the relevant patent is found to be invalid and not infringed several years after the reverse-payment settlement agreements were executed.

After careful consideration and noting that there is no precedential guidance on this issue, I conclude that prior findings of patent invalidity and non-infringement made after the reverse-payment settlement agreements are irrelevant to a rule of reason analysis. However, I conclude that the prior patent ruling is relevant to Plaintiffs' antitrust causation showing and, in this context, the ruling is admissible under Federal Rule of Evidence 403.

I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

The case before me involves allegations that four reverse-payment settlement agreements entered into by a brand-name drug manufacturer, Cephalon, Inc., and four generic drug companies constitute antitrust violations under the Sherman Act.[1] Plaintiffs claim that these settlement agreements were executed for the purpose of delaying competition from generic versions of the brand-name pharmaceutical, Provigil. Defendants, signatories to the settlement

[1] These agreements were entered into by Defendant, Cephalon, Inc. ("Cephalon"), the manufacturer of brand-name Provigil, and the following Defendant generic drug manufacturers: Barr Pharmaceuticals, Inc. ("Barr"); Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"); Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"); and Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy") (collectively referred to as the "Generic Defendants").

agreements, maintain that the agreements were pro-competitive and legitimate settlements of litigation involving Provigil and its related patent.

As a result of various settlements and the procedural postures of other related cases, the only plaintiffs who will participate in the upcoming trial are Apotex, Inc., a generic competitor, and a group of owners and operators of retail pharmacies. Over the course of this litigation, these plaintiffs have been referred to as "Individual Plaintiffs," "Retailer Plaintiffs," "Opt-Out Plaintiffs" and "Merchant Plaintiffs." The only defendants in the upcoming trial are generic manufacturers Mylan and Ranbaxy.[2]

a. Relevant Regulatory Background

Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, commonly known as the Hatch-Waxman Act, generic manufacturers are permitted to file an Abbreviated New Drug Application ("ANDA") when seeking approval from the Food and Drug Administration to market a generic version of an approved drug. An ANDA filer is able to adopt the safety and efficacy studies that the FDA previously approved in connection with a brand-name drug's New Drug Application. See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1282 (Fed. Cir. 2008).

In filing an ANDA, a generic manufacturer must demonstrate that its generic product and the approved brand-name drug share the same active ingredients and are bioequivalent. As to any patents covering the brand-name drug, the generic manufacturer must certify: (1) that the relevant patent information has not been filed with the FDA; (2) that any such patent has expired; (3) the date that such patent will expire; or (4) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Id. at

[2] More specifically the upcoming trial involves the claims Apotex has brought against Ranbaxy and Mylan and the claims the Retailer Plaintiffs have brought against Ranbaxy.

1282-83 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)). If a generic manufacturer seeks to market a generic drug prior to the expiration of patents covering the brand drug, it must file a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV)—i.e., a "Paragraph IV certification." Id. at 1283. The filing of a Paragraph IV ANDA constitutes an act of patent infringement, often prompting the patent holder to file a lawsuit. Actavis, 133 S. Ct. at 2228 (citing 35 U.S.C. § 271(e)(2)(A)).

If the patent holder files an infringement lawsuit within forty-five days of a generic manufacturer's ANDA filing, the FDA is barred from approving the generic's ANDA for a period of thirty months. 21 U.S.C. § 355(j)(5)(B)(iii). If the case is resolved during the thirty month stay, the FDA will take action on the ANDA consistent with the court's judgment. Actavis, 133 S. Ct. at 2228. However, if the case is not resolved during that period, the FDA may approve the ANDA, at which point the generic company decides whether to sell its product "at-risk" of incurring damages should the infringement case result in a judgment in favor of the patent holder. Id.

b. Relevant Factual Background

Cephalon held U.S. Reissue Patent No. 37,516 (RE '516) claiming a specific formulation of modafinil—a molecule with wakefulness-promoting properties. The RE '516 patent covered Cephalon's drug, Provigil, and, when combined with a number of FDA regulatory exclusivity periods Cephalon had obtained, it had the potential to protect Provigil from generic competition through April 6, 2015.

On December 24, 2002, the first day allowed by law, the Generic Defendants sought permission from the FDA to market generic versions of Provigil. In doing so, the four generic drug manufacturers filed Paragraph IV certifications attesting that the RE '516 patent was either invalid or not infringed by their proposed generic Provigil products. In response to these

certifications, Cephalon filed suit against the Generic Defendants for patent infringement. The parties have referred to these lawsuits as the "Paragraph IV litigation."

Between December 2005 and February 2006, the Paragraph IV litigation settled, with Cephalon paying the Generic Defendants millions of dollars in return for various business arrangements and, most importantly for purposes of this case, promises from each of the Generic Defendants to drop their respective invalidity contentions and not market a generic version of Provigil until April 6, 2012.

Pursuant to another provision of the Hatch-Waxman Act, no other company could sell generic Provigil until six months after the settling Generic Defendants began to market their versions. Thus, in order to be allowed to enter the market sooner, a competing generic—here, Apotex—would need to receive a court determination that the RE '516 patent was invalid or not infringed.

In the cases before me, the Federal Trade Commission, two putative classes of plaintiffs, the Retailer Plaintiffs and Apotex brought Actavis antitrust claims against all Defendants. Apotex also brought claims for Walker Process fraud and sham litigation against Cephalon and also sought a declaratory judgment invalidating the RE '516 Patent.

Appreciating that resolution of the antitrust claims could take many years, I commenced a patent trial in 2011. After submission of extensive testimony, I found merit in Apotex's position and declared Cephalon's patent invalid on several grounds and also unenforceable as a result of Cephalon's inequitable conduct during the procurement process. See Apotex, Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011). This ruling was subsequently affirmed by the United States Court of Appeals for the Federal Circuit, Apotex, Inc. v. Cephalon, Inc., 500 Fed.

App'x 959 (Fed. Cir. 2013), and certiorari was denied by the United States Supreme Court. See 134 S. Ct. 825 (2013).

As the antitrust case progressed, the parties subsequently litigated whether the patent ruling had a preclusive effect on certain arguments Cephalon sought to present in defending against the antitrust claims brought against it. See King Drug Co. of Florence v. Cephalon, Inc., 2014 WL 982848 (E.D. Pa. Mar. 13, 2014); F.T.C. v. Cephalon, Inc., 36 F. Supp. 3d 527 (E.D. Pa. 2014) (collectively, "collateral estoppel decisions"). These collateral estoppel decisions primarily dealt with whether Cephalon was precluded from relitigating issues decided in the 2011 patent proceedings and presenting evidence that implicated those previously litigated issues.

After extensive discovery and further motion practice, a liability trial—including the Apotex and the Retailer Plaintiffs' cases—was scheduled to begin on February 2, 2016. Prior to that date, the parties filed multiple motions in limine regarding what role, if any, the prior patent findings should play in the upcoming antitrust trial. Many of the parties' Daubert motions also touched on this issue.

In ruling on a number of Plaintiffs' Daubert motions, I summarized how the collateral estoppel decisions would shape the antitrust trial in general and the Walker Process claim against Cephalon in particular as follows:

> With trial pending, it may be useful to restate here which issues have been decided and may not be revisited: (1) the RE '516 patent is invalid due to the on-sale bar, derivation and obviousness; and (2) the materiality prong of Walker Process fraud has been established. Consequently, and as will be explained in greater detail infra, any expert opinions contrary to these holdings will not be permitted.
>
> It is also my intention to explain to the jury that these issues have been previously decided, must be accepted, and are not for their

> consideration. This explanation will come by way of instructions prior to opening statements and the taking of testimony. I will, of course, accept input from counsel as to how these concepts should be conveyed to the jury, but care will be taken to ensure that Defendants' rights in defending the antitrust allegations will be protected.

King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2015 WL 6750899, at *3-4 (E.D. Pa. Nov. 5, 2015). I also noted that my collateral estoppel decisions made clear that "[t]he fact that the patent was found invalid in the 2011 Apotex patent litigation should have no bearing on the proofs necessary to hold the Generic Defendants liable for antitrust violations . . . [and] [t]he Generic Defendants will still be able to argue, should they so choose, that settlement was pro-competitive, and that they were unaware of Cephalon's alleged fraud or the invalidity of the patent." Id. at *3 (quoting King Drug Co. of Florence v. Cephalon, Inc., 2014 WL 982848, at *13).

In the lead up to the February 2016 trial date, Defendants appealed my ruling granting certification of a Direct Purchaser class. In light of that appeal, the United States Court of Appeals for the Third Circuit stayed the February trial date as to all parties. As such, many of the motions in limine were not resolved at that time and were still pending when a new trial date was set after the Third Circuit issued its decision on the class certification appeal and the stay was lifted.

In the interim, several parties settled and, as a result, the make-up of the parties now proceeding to trial and the claims at issue have changed considerably. In short, Cephalon and the Walker Process claim brought against it are no longer part of the case. The prior collateral estoppel decisions as well as the parties' motions regarding the patent ruling were filed when Cephalon was still part of the case. Consequently, in many ways the prior collateral estoppel decisions and the parties' previously submitted arguments no longer fit the facts of the case as

presently configured. However, the parties' recent submissions have provided additional clarity and the issue as to the admissibility of the prior patent ruling is now finally ripe for final resolution.

II. LEGAL STANDARDS

Evidence is relevant if it "(a) has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. The court is afforded "very substantial discretion" in conducting the Rule 403 balancing test. United States v. Long, 574 F.2d 761, 767 (3d Cir. 1978).

III. DISCUSSION

At the recent pretrial conference, the parties again presented argument regarding the admissibility of the prior patent ruling. Prior to that conference, I had understood Plaintiffs' position to be that the prior patent ruling was relevant and admissible in the context of the entire trial. However, through the parties' pretrial memoranda and argument presented at pretrial conference, it became clear that Plaintiffs contend that the prior patent ruling is specifically relevant and admissible in the context of causation. Defendants have continued to maintain that any mention of the outcome of the patent trial—in either the rule of reason or causation portion of trial—would be highly prejudicial.

In light of this narrowed argument, I invited the parties to submit additional briefing on whether the prior patent ruling is relevant and otherwise admissible in the context of the causation part of the case.

a. Admissibility of Prior Patent Ruling in the Antitrust Violation Context

Defendants have consistently argued that, under Actavis, the prior patent ruling is irrelevant to Plaintiffs' claims because that ruling postdates the settlement agreements by several years. Defendants assert that the parties' views regarding the patent's strength or weakness and how those views impacted the decision to enter into the challenged settlement agreements should be examined on an ex ante basis, thus excluding a subsequent ruling on the patent.

After reviewing the additional arguments the parties recently presented, I agree with Defendants that the patent ruling, which occurred approximately five years after the settlement agreements were executed, is not admissible to establish whether Defendants violated the antitrust laws under an Actavis rule of reason framework. My conclusion rests primarily on the fact that the Actavis rule of reason analysis is focused on whether the settlements were reasonable at the time they were entered into – in late 2005 and early 2006.

In fact, in analyzing the admissibility of expert testimony, I previously held that the relevant rule of reason analysis is conducted on an ex ante basis, that is, as of the time the settlements were executed. See King Drug Co. of Florence, Inc., 2015 WL 6750899, at *12 ("[E]xperts should limit their testimony to exploration of the infringement opinions and arguments raised by the parties at the time of the Paragraph IV litigation on an ex ante basis"); see also King Drug Co. of Florence, Inc., 2015 WL 5783603, at *6. After reexamination of these rulings, I stand by that conclusion, notwithstanding the fact that the parties proceeding to trial have been significantly pared down.

Legal scholars and other courts presented with this issue concur with the ex ante interpretation of Actavis. See Aaron Edlin, et al., The Actavis Inference: Theory and Practice, 67 Rutgers U.L. Rev. 585, 617 (2015) ("[T]he antitrust analysis of a reverse-payment settlement

should be made on an *ex ante* basis, as of the date of the settlement itself."); In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 753 (E.D. Pa. 2015) ("In conducting the rule of reason analysis, the Court will evaluate the [ ] Settlement's reasonableness at the time it was entered into."); In re Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 544 (D.N.J. 2014) ("In this case, in order to approximate the amount of Pfizer's alleged consideration to Ranbaxy, it is necessary to consider the monetary value of Pfizer's claim at the time of the settlement."). This interpretation is also consistent with the general principle that "the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into." Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1306 (11th Cir. 2003).

Against this backdrop, I conclude that the patent ruling, which postdates the contested settlement agreements, is irrelevant under the ex ante framework mandated by the Actavis rule of reason analysis. See Aaron Edlin, et al., The Actavis Inference: Theory and Practice, 67 Rutgers U.L. Rev. 585, 586 (2015) ("The antitrust question depends upon the *ex ante* prospects in patent litigation and not *ex post* litigation of the patent by a patent court or by the antitrust court considering the settlement. Litigating the patent is thus of limited probative value and not dispositive regarding a potential antitrust violation.")

In addition to the relevance question, Defendants also argue that introduction of the prior patent ruling would result in significant jury confusion and unfair prejudice. Given the ex ante focus of the Actavis rule of reason framework, and to the extent that a Rule 403 analysis applies, I agree with Defendants that whatever probative value the patent rulings would have in the rule of reason portion of the case would be substantially outweighed by the risk of jury confusion and unfair prejudice. The fact that the patent was found to be invalid several years after the settlement agreements were finalized has little bearing on whether the decisions to enter into

those agreements were reasonable in light of the circumstances in existence at that time. I am persuaded that the jury will be unable to reconcile and abide by that temporal nuance if presented with evidence that the patent was invalidated several years after the agreements in question were reached. This reality may also result in unfair prejudice to Defendants.

As noted above, I conclude that the patent ruling is not relevant in an ex ante rule of reason analysis. But, even if relevant, I conclude that whatever marginal probative value the 2011 patent ruling may have in the context of the rule of reason analysis is substantially outweighed by the risk of jury confusion and unfair prejudice. Whether the prior patent ruling is admissible in the context of causation is a separate question.

b. Admissibility of the Prior Patent Ruling in the Antitrust Causation Context

Causation is an essential element of a private plaintiff's antitrust case. Out Front Prods., Inc. v. Magid, 748 F.2d 166, 169 (3d Cir. 1984). To demonstrate causation, the Clayton Act requires plaintiffs to prove that their injuries were caused "by reason of" anticompetitive conduct. 15 U.S.C. § 15(a). "The 'by reason of' language requires both a showing that defendant's actions were the but-for and the proximate cause of the injury." In re Wellbutrin, 133 F. Supp. 3d at 763(citing Assoc. Gen. Contractors of Calif. v. California State Council of Carpenters, 459 U.S. 519, 531 (1983)). In the context of a reverse-payment settlement claim, plaintiffs must prove that the settlements caused a delay in generic competition. See King Drug Co. of Florence, 88 F. Supp. 3d 402, 421-23 (E.D. Pa. 2015).

Plaintiffs have offered two theories as to how the reverse-payment settlements delayed generic entry, thereby causing economic injury. Plaintiffs describe these two theories as follows:

> But for the Cephalon-Mylan and Cephalon-Ranbaxy reverse-payment agreements, [1] Mylan and/or Ranbaxy would have launched at-risk [or 2] defeated the '516 patent, triggering their 180-day exclusivity. Under those circumstances, Apotex would

> have obtained final FDA approval and launched its own generic modafinil product at least when the first filers' 180-day exclusivity expired.

(Dkt. No. 06-2768, Doc. No. 1095, Pls.' Pretrial Mem. p. 28.)

Relevant to the question presently before me is the first theory of causation. Under that theory, Plaintiffs argue that but for the settlements agreements, Mylan or Ranbaxy would have pursued the Paragraph IV litigation and launched their generic products after the expiration of the automatic thirty month stay, but prior to judgment being entered in the Paragraph IV litigation.

Plaintiffs explain that the prior patent rulings are relevant to this at-risk launch theory of causation. Plaintiffs raised this argument in response to two questions included on Defendants' proposed jury verdict form. These questions are:

> Have Plaintiffs proved that if Cephalon and Ranbaxy had not entered into their patent litigation settlement, Ranbaxy would have lawfully launched an FDA-approved generic Provigil product in 2006?
>
> . . .
>
> Have Plaintiffs proved that if Cephalon and Mylan had not entered into their patent litigation settlement, Mylan would have lawfully launched an FDA-approved generic Provigil product in 2006?

(Dkt. No. 06-2768, Doc. No. 1119-4, Defs.' Proposed Verdict Form, pp. 6 and 9.) Plaintiffs argued that the inclusion of the term "lawful" indicated Defendants' position that Plaintiffs must:

> offer evidence from which the jury could conclude that the patent was invalid or not infringed and [ ] therefore an at-risk entry would've been lawful, because of course if the at-risk entry was unlawful the defendants will argue then the entry didn't cause any damages, because in the end they would not be allowed to stay on

the market.

(Pretrial Conf., May 16, 2017, Tr. 45:16:21.) Based on all of the above, Plaintiffs urge that the prior patent ruling is highly probative and relevant to the question of whether an at-risk launch would have been lawful.

After hearing Plaintiffs' argument, counsel for both Mylan and Ranbaxy stated that they were willing to withdraw the word "lawful" from their proposed verdict form. (Id. at 55:16-22; 56:22-57:1.) Plaintiffs convincingly responded that even if that word was removed from the proposed verdict form, the issue would not be resolved because they still must prove that their presence in the market would have been lawful. Plaintiffs explain that the only two courts to have considered the elements of an at-risk launch theory of causation have both held that a plaintiff must demonstrate that a generic defendant's decision to launch at-risk would be "lawful"—meaning that the brand company's patent is invalid or not infringed by the generic product launched at-risk, In re Nexium (Esomeprazole) Antitrust Litigation, 842 F.3d 34 (1st Cir. 2016) and In re Wellbutrin XL Antitrust Litigation, 133 F. Supp. 3d 734 (E.D. Pa. 2015). After careful consideration of these decisions, I agree that Nexium and Wellbutrin support Plaintiffs' position.

In Nexium, the plaintiffs offered multiple arguments, including an at-risk launch theory, regarding how the defendants' reverse-payment settlements caused harm. 842 F.3d at 61-62. At the close of plaintiffs' case, the district court granted defendants' motion for judgment as a matter of law with regard to any "causal mechanism" based on patent invalidity, finding "no adequate evidence that any of [the Nexium] patents would be adjudicated invalid." Id. at 49.

On appeal, the United States Court of Appeals for the First Circuit held that the district court "did not err by requiring some evidence of the patents' invalidity or non-infringement

before allowing the plaintiffs to pursue an at-risk launch theory" of causation because without such evidence the underlying patents would have operated as an independent bar to the generic's launch. Id. at 63. The First Circuit rejected the plaintiffs' argument that "they should not have to prove patent invalidity or noninfringement to be able to present their at-risk launch causation theory." Id. at 62-64.

In reaching its conclusion, the First Circuit recognized that the district court's judgment as a matter of law ruling on causation did not prevent nor prejudice plaintiffs' ability to offer evidence regarding the assessment of risk in the context of showing an antitrust violation under the Actavis rule of reason framework. Id. at 64.

Like Nexium, the plaintiffs in Wellbutrin also sought to proceed on an at-risk launch theory of causation. The district court granted defendants' motion for summary judgment on the issue of causation because the plaintiffs offered no evidence of invalidity or non-infringement in support of their at-risk launch theory. 133 F. Supp. 3d at 764-767. Citing City of Pittsburgh v. West. Penn Power Company, 147 F.3d 256 (3d Cir. 1998), the district court noted that "an independent regulatory scheme can cut off the necessary chain of causation." Wellbutrin, 133 F. Supp. 3d at 763-764.

Applying that principle in the context of Plaintiffs' at-risk launch theory of causation, the court reasoned that "the existence of a valid and uninfringed patent would interfere with the plaintiffs' chain of causation: a valid patent independently precludes competition apart from any agreement and an 'at-risk' launch is unlawful absent a later finding of patent invalidity or non-infringement." Id. at 764-65 (emphasis added) (internal citations and alterations omitted). As such, the court held that to succeed under an at-risk theory of causation, the plaintiffs would have to show that reverse-payment settlements prevented generic entry, rather than the underlying

patents and, in order to do so, the plaintiffs would have to offer evidence that the underlying patent would have been invalidated or the generic product would not have infringed the underlying patent. Id. at 765. As the plaintiffs had offered no such evidence, the district court entered summary judgment in defendants favor. Id. at 764-67.

The clear import of Nexium and Wellbutrin is that a plaintiff must offer some evidence of non-infringement or patent invalidity in order to proceed on an at-risk launch theory of causation. The fact that the patent in question has been found to be invalid and non-infringed is relevant evidence on that required proof.

Against this backdrop, I agree with Plaintiffs that evidence of a patent's subsequent invalidation is highly probative to the lawful launch question. Additionally, nothing in the albeit limited case law suggests that the strict ex ante lens that applies to the rule of reason under Actavis must also apply to the question of causation.[3] In light of the foregoing, I conclude that the prior patent ruling is highly probative in the context of Plaintiffs' at-risk launch theory of causation.

c. Trial Structure

This case is unique because the patent was found to be invalid after settlement of the Paragraph IV litigation but prior to the antitrust trial—a procedural posture that all involved have endeavored to grapple with. As far as I am aware, this case will be the second Actavis reverse-payment settlement case to go to trial. Consequently, there is little guidance on how to structure

[3] The Supreme Court did not address causation in Actavis. This silence is likely attributable to the fact that the plaintiff was the Federal Trade Commission and the claims were equitable in nature. In antitrust cases, the FTC is held to a less stringent causation standard than private plaintiffs. See 15 U.S.C. § 45 (The FTC need only prove that a defendant's conduct is "likely to cause" injury). As such, although the Actavis Court stated that "it is normally not necessary to litigate patent validity to answer the antitrust question," 133 S. Ct. at 2236, that statement does not address a private plaintiff's causation requirement nor does it preclude examination of the validity of the patent where necessary.

this case. In Actavis, the Court allowed wide discretion for lower courts to structure rule of reason antitrust litigation, explaining:

> As in other areas of law, trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences. We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.

133 S. Ct. at 2238 (internal citations omitted).

Given the discretion conferred by Actavis, and my legal conclusions regarding the admissibility of the prior patent ruling, I conclude that the upcoming liability trial will be divided into two phases. The first phase will involve only proofs regarding the alleged antitrust violations under the rule of reason. The jury verdict form will contain questions pertaining only to the antitrust violation under the rule of reason analysis. Consistent with my conclusions set forth above, the prior patent ruling will not be mentioned by the court, witnesses or attorneys during this first phase.

If the jury answers the violation questions in Plaintiffs' favor, a second phase involving causation and injury will commence. There, I will inform the jury that the patent was determined to be invalid in a subsequent proceeding.[4] However, in light of Defendants' legitimate concerns regarding prejudice, the jury will not be told that I personally made that prior ruling or that it was

[4] I have also considered Plaintiffs' position that all findings of fact from the invalidity portion of the patent trial be read to the jury by way of stipulation. This is an overly expansive position. Doing so would place a heavy hand on the unfair prejudice side of the scale. I must balance the need for the jury to understand how these facts fit in an antitrust case with the risk of unfair prejudice to the Defendants. Such an extensive recitation is unnecessary and the probative value is substantially outweighed by the risk of jury confusion and/or unfair prejudice under Rule 403.

affirmed on appeal. Rather, I will generally inform the jury that these issues were decided in a prior proceeding without identifying the decision maker.

A jury instruction will also be given that emphasizes that Mylan and Ranbaxy were not involved in the patent procurement process or the subsequent finding of invalidity. This jury instruction will also explain that admission of this evidence is for a specific and limited purpose—i.e., Plaintiffs' causation theory—and that it is just one piece of evidence that may be considered on the issue of causation. These additional instructions will also decrease the risk of unfair prejudice.

During this phase of the trial, counsel will be given an opportunity to present short opening and closing statements. If relevant, evidence from the first phase may be incorporated and other relevant causation/injury evidence may also be offered. Specific causation and injury questions will then be posed to the jury.

This process adequately addresses Defendants' prejudice concerns.[5] Defendants argued that they will be unfairly prejudiced because they were not participants in the prior patent proceedings. However, that argument misses the mark because neither Defendant was the patent holder and thus could not logically be a part of the patent proceeding. Surely, both the Court and counsel can clearly explain that point to the jury. Defendants are also free to present evidence of

[5] Following the pretrial conference, I provided Defendants with yet another opportunity to explain their positions regarding prejudice. Both Mylan and Ranbaxy submitted further briefing. I have carefully considered those supplemental briefs but, as explained above, the risk of unfair prejudice, as articulated by Defendants, does not substantially outweigh the probative value in the context of causation.

I also note that Defendants argued that the jury will undoubtedly assume that a judge invalidated the patent and that this assumption will result in unfair prejudice. I agree with Plaintiffs that this argument assumes that evidence is unfairly prejudicial if it is highly probative and supports the opposing parties' position. Even assuming this assumption constitutes "unfair prejudice," the supposed risk identified by Defendants does not substantially outweigh the probative value of the evidence.

other considerations that indicate that Defendants would not have launched at-risk and may argue that, when evaluating the evidence of causation, the jury should not afford the prior patent ruling any weight in light of the timing of events.

IV. CONCLUSION

For the foregoing reasons, I conclude that the liability portion of the trial will be divided into two phases – violation and causation – and only during the second phase regarding causation will the jury be informed that the relevant patent was invalidated in a proceeding which occurred after the Paragraph IV litigation settled. An appropriate Order follows.